

## CLAIMS

1. Use of cetirizine, an individual optical isomer thereof or a pharmaceutically acceptable salt thereof for the preparation of a medicament intended for preventing the onset of asthma in a patient.
2. Use of cetirizine, an individual optical isomer thereof or a pharmaceutically acceptable salt thereof for the preparation of a medicament intended for preventing the onset of asthma in a patient, the said medicament being administered to the patient prophylactically prior to the onset of asthma.
3. Use of cetirizine, an individual optical isomer thereof or a pharmaceutically acceptable salt thereof for the preparation of a medicament intended for preventing the sensitisation of patient at risk of developing asthma diseases.
4. Use according to claim 1, 2 or 3, wherein the salt is the cetirizine dihydrochloride.
5. Use according to claim 1, 2, 3 or 4, wherein the patient is an infant or a child.
6. Use according to claim 5, wherein the patient is aged 1 to 4 years.
7. Use according to any one of claims 1 to 6, which comprises administering a daily dosage from about 0,0005 mg to about 2 mg of said cetirizine, said individual optical isomer thereof or said pharmaceutically acceptable salt thereof, per kg of body weight per patient.
8. Use according to claim 7, which comprises administering a daily dosage from about 0,05 mg to about 1 mg per kg of body weight per patient.
9. Use according to any one of claims 1 to 8, which comprises administration 1 to 3 times a day.
10. Use according to any one of claims 1 to 10, wherein said cetirizine, said individual optical isomer thereof or said pharmaceutically acceptable salt thereof is administered orally.
11. A method for preventing the onset of asthma which comprises administering to a patient a therapeutically effective amount of cetirizine, an individual optical isomer thereof or a pharmaceutically acceptable salt thereof.

Table 1: Occurrence of Asthma by Baseline Atopic Characteristics Placebo ITT  
Population (n = 397)

		Normal (%)	Elevated (%)	RR for developing asthma in presence of elevated marker [95% CI]	Log-Rank Test p value
5					
	Total IgE (PRIST)*	(33.5)	(43.6)	1.3 [1.0 ; 1.7]	0.027
10					
	IgE Grass pollen (GX1)*	(35.0)	(58.8)	1.7 [1.2 ; 2.3]	< 0.001
	IgE HDM (D1)*	(34.7)	(51.5)	1.5 [1.1 ; 2.0]	0.005
15					
	IgE Cat dander (E1)*	(33.2)	(47.1)	1.4 [1.0 ; 1.9]	0.032
	IgE Egg (F1)*	(30.7)	(39.3)	1.3 [0.9 ; 1.8]	0.152
	IgE Milk (F2)*	(36.0)	(40.9)	1.1 [0.9 ; 1.5]	0.250
20					
	IgE HDM+Grass Pollen	(32.9)	(53.7)	1.6 [1.2 ; 2.1]	<0.001
	Eosinophil count	(34.9)	(47.6)	1.4 [1.0 ; 1.9]	0.066

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ITT Intention-to-treat  
RR relative risk  
CI confidence interval  
( )\* Pharmacia & Upjohn Diagnostics references

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HDM House Dust Mite  
Elevated values Total IgE :  $\geq 30$  kU/l,  
Specific IgE :  $\geq 0.35$  kUA/l,  
Eosinophils :  $> 0.7$  giga/l

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Table 2: Occurrence of Asthma by Treatment in the ITT population

5		Placebo	Cetirizine	RR for developing	Log-Rank
		(%)	(%)	asthma when cetirizine treated [95% CI]	Test p value
	ITT population	(38.0)	(37.7)		0.973
				[0.8; 1.2]	
10	Subgroups with elevated IgE or eosinophils at baseline				
	Total IgE (PRIST)*	(43.6)	(38.1)	0.9 [0.7 ; 1.1]	0.391
	IgE Grass pollen (GX1)*	(58.8)	(27.8)	0.5 [0.3 ; 0.9]	0.002
15	IgE HDM (D1)*	(51.5)	(28.6)	0.6 [0.3 ; 0.9]	0.005
	IgE Cat dander (E1)*	(47.1)	(40.6)	0.9 [0.6 ; 1.3]	0.610
	IgE Egg (F1)*	(39.3)	(31.2)	0.8 [0.6 ; 1.1]	0.292
20	IgE Milk (F2)*	(40.9)	(30.7)	0.7 [0.5 ; 1.0]	0.140
	IgE HDM+Grass pollen	(53.7)	(34.2)	0.6 [0.4 ; 0.9]	0.006
25	Eosinophil count	(47.6)	(42.7)	0.9 [0.6 ; 1.3]	0.674
	ITT	Intention-to-treat			
	RR	relative risk			
30	CI	confidence interval			
	( )*	Pharmacia & Upjohn Diagnostics references			
	HDM	House Dust Mite			
	Elevated values	Total IgE : ≥30 kU/l, Specific IgE : ≥0.35 kUA/l, Eosinophils : >0.7 giga/l			
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